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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/834,747 | 04/13/2001 | Hal Sternberg | BIOT008 | 4271 |

24353 7590 08/12/2003

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EXAMINER

CHOI, FRANK I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1616

DATE MAILED: 08/12/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,747

Applicant(s)

STERNBERG, HAL

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19,22,25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 22, 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant amends the claims by indicating that the pharmacological means does not include sodium bicarbonate. However, the Specification does not indicate that sodium bicarbonate may be excluded from the pharmacological means. As such, it does not appear that one of ordinary skill in the art would immediately envisage a negative limitation excluding sodium bicarbonate from the pharmacological means from the disclosure as originally filed.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Taylor et al. (US Pat. 5,514,536) for the reasons of record and the further reasons below.

Taylor et al. expressly discloses a method of administering a blood substitute containing electrolytes, including potassium, sodium, magnesium, calcium, chloride, buffer, including bicarbonate, simple sugar and an oncotic agent, including starch, wherein the subjects are under anesthesia and are hooked up to an oxygenator falling within the scope of applicant's claims (See Examples and Claims). The compositions and/or procedures will cause a reduction in carbon dioxide levels.

Examiner has duly considered Applicant's arguments but deems them unpersuasive. Examiner acknowledges that to anticipate a claim the prior art must contain all the elements and limitation of the claim. However, under current case law, an element or limitation can be inherent in the prior art product or method. See *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Applicant argues that because the prior art solutions may contain hydrogen carbonate and dihydrogen phosphate to combat acidosis that the two part component system is not taught in the prior art. However, Applicant has only shown that the prior art solutions may contain the same to combat acidosis and have not shown that use of an oxygenator will not reduce acidosis. Further, the claims clearly state that the risk of acidosis/acidemia is reduced, as such, the risk is still there. Thus, the optional addition of above buffers is not precluded by the claims and does not take away from the inherency of the reduction of CO₂ sufficient to reduce the risk of acidosis/acidemia. Since the oxygenator will inherently reduce the levels of carbon dioxide, the

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burden is on Applicant to show the prior art method or product cannot produce the result, i.e. reduction of the risk of acidosis/acidemia. See *In re King*, 231 USPQ 136 (Fed. Cir. 1986); See also *In re Best*, 195 USPQ 430, 433 (CCPA 1977). Applicant requests that Examiner provide a reference of record or affidavit, however, this is not required. Applicant's Specification clearly indicates that oxygenators are suitable means for reducing the risk of acidosis/acidemia (Specification, pgs. 4, 5). The burden is on Applicant to show that the prior art method will not reduce the risk of acidosis/acidemia and attorney argument does not appear to constitute evidence meeting said argument. See *In re Schulze*, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 43 USPQ2d 1362 (Fed. Cir. 1997).

In response to applicant's arguments, the recitation "does not comprise a conventional biological buffer" as not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 152, 88 USPQ 478, 481 (CCPA 1951).

Finally, the use of the negative limitation "a pharmacological means not including sodium bicarbonate" does not overcome the rejection as the maintenance solution does not have sodium bicarbonate but potassium bicarbonate (Column 20, lines 5-25). See also arguments set forth in the Advisory Action (3/21/2003) relative to the negative limitation.

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Claims 1-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Segall et al. (U.S. Pat. 5,702,880) or Segall et al. (US Pat. 5,571,801).

Segall et al. expressly discloses a method of administering a blood substitute containing potassium, sodium, magnesium, calcium, chloride, bicarbonate, glucose, Herastarch, wherein the subjects are under anesthesia and are hooked up to an oxygenator falling within the scope of applicant's claims (See Examples and Claims). The compositions and/or procedures will cause a reduction in carbon dioxide levels.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above. With respect to Applicant's arguments concerning the use of bicarbonate, it is noted that like above, the bicarbonate is used if needed. As such, similar to above, the reference to bicarbonate does not show that the prior art product does not reduce carbon dioxide levels sufficient to reduce the risk of acidosis/acidemia. Also, the fact that the '880 patent does not discuss acidosis/acidemia is not sufficient to overcome the rejection herein as the reduction in carbon dioxide levels is inherent in the product and method or the prior art. The burden falls on Applicant to show that the prior art product and method cannot produce the same result, i.e. the reduction of carbon dioxide levels sufficient to reduce the risk of acidosis/acidemia. With respect to the negative limitation, the limitation reads "a pharmacological means not including sodium bicarbonate for reducing the CO₂ level of a subject in an amount sufficient to reduce the risk of acidosis/academia". Applicant has not shown that sodium bicarbonate as used in the prior art reduces CO₂ levels, as such, Applicant has not shown that that the negative limitation overcomes the prior art.

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Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

August 11, 2003



S. MARK CLARDY
PATENT EXAMINER
GROUP 1200
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